REMARKS

Status of the claims

Claims 1-6, 8-13, 17, 18, 20, 40, 41, 43, 46 and 47 were pending and claims 11-13, 17, 20, 40, 41, 43, 46 and 47 were withdrawn from further consideration. Claims 1-6, 8-10 and 18 stand rejected.

Claims 11-13, 17, 20, 40, 41, 43, 46 and 47 are cancelled without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of those claims in another application. Claims 2, 6, 10 and 18 are amended.

Claim objections

The Office has objected to claim 2 by alleging that the phrase "essentially consists of" is unclear. Claim 2 is amended to remove the word "essentially."

The Office has objected to claim 6 by alleging that claim 6 fails to further limit claim 5 "since both claims [use] open claim language," (Office action, p. 2, line 17-18.) Claim 6 is amended to remove the word "essentially."

In view of the amendments made, Applicants believe that the claims 2 and 6 are unobjectionable and therefore ask that the Office remove its objection to those claims.

Specification

The Office has objected to the title of the invention for allegedly not being descriptive. The title has been changed from "Novel Sodium Channel" to "Murine Type III Sodium Channel Compositions and Methods of Use Therefor."

Information disclosure statement

The Office contends that the IDS, which was filed on 09/17/2008, fails to comply with 37 CFR § 1.98(a)(2) for allegedly failing to list the date of disclosure for the disclosed GenBank® accession references. Applicants submit herewith a courtesy copy of each GenBank® reference and a revised form PTO-1449, which includes the dates of disclosure for those references.

Claim rejections – 35 USC § 101

Claim 10 stands rejected for allegedly being directed to non-statutory subject matter under 35 USC § 101. The Office alleges that "claim 10 reads on the presence of the

nucleic acid inside a cell or an animal." Applicants traverse, since the nucleic acid is an "isolated nucleic acid molecule." .

However, in the interest of facilitating prosecution and while reserving the right to pursue the subject matter of the original claim 10 in another application, claim 10 is amended to be directed to an "isolated" host cell. Support for this amendment can be found e.g. at paragraph [0242] in the specification-as-published. No new matter is presented in this amendment.

In view of the amendment to claim 10, Applicants request that the rejection of this claim under 35 USC § 101 be withdrawn and the claim allowed.

Claim rejection – 35 USC § 112, second paragraph

Claim 18 stands rejected under 35 USC § 112, second paragraph as allegedly being indefinite. The Office alleges that the phrase "polypeptide activity in a cell" is indefinite. Applicants traverse.

As the Office admits, polypeptide activity has several clear meanings, including "sodium current, the closing and opening of the channel, or the signal transduction caused by the $mNa_v1.3$ α subunit," (Office action, p. 4, lines 14-15.)

However, in the interest of facilitating prosecution and while reserving the right to pursue the subject matter of the original claim 18 in another application, claim 18 is amended to be directed to "sodium current through a $mNa_v1.3$ channel." Support for this amendment can be found e.g. at paragraph [0242] in the specification-as-published. No new matter is presented in this amendment.

In view of the amendment to claim 18, Applicants request that the rejection of this claim under 35 USC § 112, second paragraph be withdrawn and the claim allowed.

Claim rejection – 35 USC § 112, written description

Claim 18 stands rejected under 35 USC § 112 for allegedly failing to comply with the written description requirement. The Office alleges that "Applicant has not provided any information regarding the identifying structural characteristics of the modulator of the $mNa_v1.3$ α polypeptide," (Office action, p. 5, lines 5-7.)

Claim 18 is amended to be directed to a modulator that is a "depolarizing voltage" and to an effect of that modulator on the channel, which is the opening of the $mNa_v1.3$

channel and the passing of a sodium current through it. Support for this amendment can be found in the working example 3 at paragraph [0242] in the specification. No new matter is presented in this amendment.

In view of the amendment to claim 18, Applicants request that the rejection of this claim under 35 USC § 112 be withdrawn and the claim allowed.

Claim rejection – 35 USC § 101/112

Claims 1-6, 8-10 and 18 stand rejected under 35 USC § 101/112 for allegedly lacking utility. The Office asserts that "the claimed invention is not supported by either a credible, specific and substantial utility or a well established utility," (Office action, p. 6, lines 22-24. The Office appears to base its rejection upon its asserted belief that "[n]ovel biological molecules lack well established utility and must undergo extensive experimentation; the instant specification [allegedly] does not teach any functional characteristics of the $mNa_v1.3$ α subunit; [and] [t]he specification does not disclose the polypeptides in the context of a cell or organism or any methods or working examples that indicate the polypeptides [are] involved in any activities or disease states," (Office action, p. 6, lines 24-25 and p. 7, lines 13-17.)

The Office does however acknowledge in the Office action that "[t]he specification asserts the following utilities: 1) to screen test compounds for drug discovery, 2) to provide diagnostic assays, prognostic assays, monitoring clinical trials, and pharmacogenetics, 3) predictive medicine, [and] to provide a method of treatment including therapeutic and prophylactic," (Office action, p. 7, line 24 – p. 8, line 4.) However, the Office asserts that "[s]ince the utility is not presented in mature form and significant further research is required, the asserted utilities are not substantial," (Office action, p. 7, lines 20-12.)

Applicants respectfully point out that the standard for "substantial" utility does not include "mature form." The Office's assertion that the research is not mature and therefore the utility is not substantial is improper. The standards for "specific and substantial" are set forth in the MPEP and in the underlying case law.

According to MPEP 2107 II (A)(3) and (B)(1), "[a]n invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or

applications of a product or process), and (ii) the utility is specific, substantial, and credible. The standard for utility, as set forth in the rules, requires that utility be evaluated in terms of the perspective of reasonable utility to one of ordinary skill in the art. If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility."

Applicants remind the Office that the specification discloses that the novel brained-expressed type III sodium channel mNav1.3 α subunit, when expressed in a physiological relevant system and tested using art recognized methodologies for physiological activity (i.e. patch clamp), unequivocally demonstrates sodium channel activity as exemplified by sodium currents (see specification, Example 3 and Figure 3 and 4.) According to case law, "[a]ll that is required is that the tests be "*reasonably* indicative of the desired [pharmacological] response," (*Nelson*, 626 F.2d at 856, 206 USPQ at 884, as qutoted in Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895, 1899 (Fed. Cir. 1996; (emphasis added.)) One of ordinary skill in the art would reasonably expect and find credible that the instant murine ortholog of a type III sodium channel, in view of its demonstrated physiological sodium channel activity and homology to human and rat type III sodium channels, would have the specific and substantial utility as set forth in the specification and acknowledged by the Office.

Furthermore, case law instructs us that "the PTO has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility," (*In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995.))

Applicants submit that the Examiner has failed to present a prima facie case demonstrating lack of utility for the claimed invention. Even if the Examiner believes that the "asserted specific and substantial utility is not credible," an opinion to which the Applicants disagree, then according to the MPEP (2107 II(c)(2)) "a prima facie showing of no specific and substantial credible utility *must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial*

utility asserted by the applicant for the claimed invention. The prima facie showing *must contain* the following elements: (i) an explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible; (ii) support for factual findings relied upon in reaching this conclusion; and (iii) an evaluation of all relevant evidence of record, including utilities taught in the closest prior art," (emphasis added.) The Office has not done this.

The Office, in its failure to "establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention, [failure to provide any] factual findings relied upon in reaching this conclusion, [and failure to evaluate] utilities taught in the closest prior art," has failed to establish an prima facie case for a lack of utility for the claimed invention.

In view of the arguments presented above, in which the Applicants assert (a) that the specification provides specific, substantial and credible utility for the claimed invention, and (b) that the Office has failed to provide a prima facie case of lack of utility under 35 USC § 101/112, Applicants respectfully request that the rejection of claims 1-6, 8-10 and 18 under 35 USC § 101/112 be withdrawn and the claims allowed.

CONCLUSION

Applicants believe that the claims are in a condition for allowance and request that the Office issue a notice of allowance. However, should any outstanding issues remain, Applicants invite the Examiner to contact the undersigned Agent.

Respectfully submitted,

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